

# Disease burden and care-seeking behavior for IBS-C patients in the United States in the era of COVID-19

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## INTRODUCTION

Irritable bowel syndrome with constipation (IBS-C) is a chronic disorder of gut-brain interaction that has a significant negative impact on patients. The COVID-19 pandemic has had a significant impact on patient outcomes and access to healthcare, but its impact on patients with IBS-C is unknown

## OBJECTIVE

To examine disease burden and care-seeking behavior of patients with IBS-C during the pandemic

## METHODS

### Data Collection

- Data were collected through two observational, cross-sectional, online surveys of U.S. adults (aged  $\geq 18$  years)
  - One survey used a random stratified sampling framework to ensure a demographic composition representative of the United States, according to the U.S. Census Bureau 2014–2018 American Community Survey 5-Year Estimate
  - The nationally representative sample was enriched by a second survey requiring that participants pre-qualify with irritable bowel syndrome (IBS) prior to enrolling based on self-report
- Surveys were fielded for 1 week each month from August 2020 through October 2020; data were collected from approximately 2000 representative-sample and 400 enriched-sample participants each month
- Survey participants were recruited from internet panels that employed digital fingerprinting (using unique characteristics of each participant) to validate responses. Only validated participants entered the survey and multiple quality processes screened data to prevent fraudulent responses. Quality control measures were implemented throughout the data-collection process to identify fraudulent responses or participants who attempted to submit  $\geq 1$  completed survey. All data were self-reported

### Survey Design

- An IBS/chronic idiopathic constipation (CIC)-specific module, developed by the study authors, was included in a larger health survey requiring certain questions to be answered by all participants: demographics, comorbid conditions, health-related quality of life (Generalized Anxiety Disorder scale 7 [GAD-7] items,<sup>1</sup> Patient Health Questionnaire 9 [PHQ-9] items,<sup>2</sup> and Veterans RAND 12 items [VR-12]),<sup>3</sup> resource utilization, and work productivity
- Participants selecting "IBS," "constipation (chronic, or more than occasional)" (constipation) or "diarrhea (chronic, or more than occasional)" (diarrhea) in the comorbid condition checklist were routed to the IBS/CIC-specific module. Participants who did not select these conditions continued with the survey questions asked of all participants
- The module and survey were reviewed by an Institutional Review Board before fielding began in August 2020

### Cohort Definition

- The IBS-C cohort was selected based on the Rome IV criteria (referred to herein as the "IBS-C Rome IV cohort" or "patients")<sup>4</sup>
- Cohort selection was determined on the following inclusion and exclusion criteria
  - Inclusion criteria (IBS-C Rome IV cohort):
    - Participants aged  $\geq 18$  years and residing in the United States
    - Participants who self-reported IBS, constipation, or diarrhea in the survey comorbid condition checklist and met the Rome IV criteria for IBS-C
  - Exclusion criteria:
    - Participants who self-reported IBS, constipation, or diarrhea in the survey comorbid condition checklist but did not meet Rome IV criteria for IBS-C
    - Participants who did not self-report IBS, constipation, or diarrhea in the survey comorbid checklist were eligible to be matched controls. Controls were matched to the IBS-C cohort, 1:1, by age, sex, region, and Charlson Comorbidity Index score

### Analysis

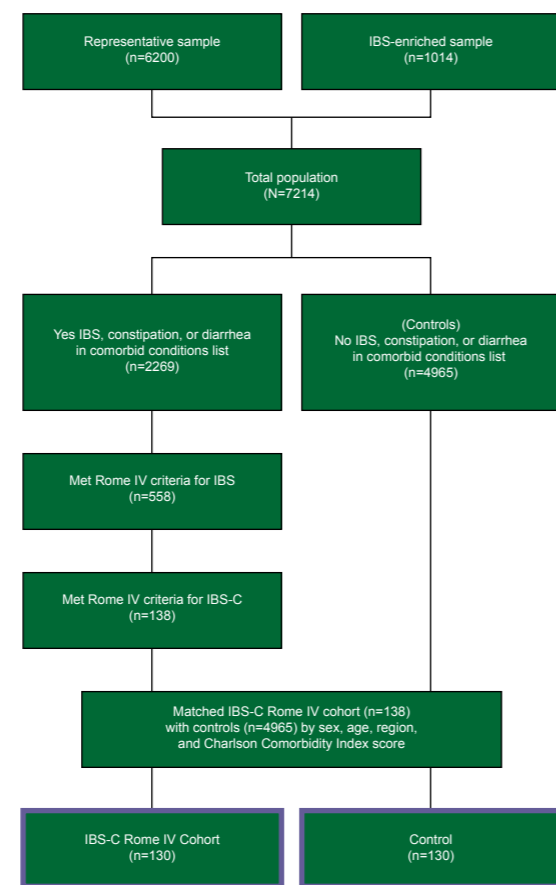
- Outcomes included anxiety, depression, health-related quality of life, all-cause healthcare resource utilization, productivity, patient and disease characteristics, symptom frequency and severity, medication use, and care-seeking behaviors
- Categorical data were described by percentage, and continuous data were described by mean and standard deviation
- For comparisons between the cohort and control groups, chi-squared analyses and analysis of variance tests were conducted for categorical and continuous data, respectively. Statistical comparisons were made with two-sided tests at the  $\alpha = 0.05$  significance level. All analyses were carried out with unweighted data

## RESULTS

### Survey and Cohort Populations

Of 7214 total survey participants, 138 met the Rome IV criteria for IBS-C. Matching resulted in a sample of 130 patients with IBS-C and 130 controls (Figure 1)

Figure 1. Matched IBS-C Rome IV cohort and controls



IBS, irritable bowel syndrome; IBS-C, irritable bowel syndrome with constipation.

### Demographics

The mean age of patients with IBS-C was 45.1 years, with the majority being female (79.2%), white (82.3%), and classified as overweight (body mass index, 27.4 lbs/in<sup>2</sup>) [Table 1]

Table 1. IBS-C Rome IV cohort vs. control demographics

	IBS-C Rome IV cohort (n=130)	Control (n=130)	p value
<b>Sex, %</b>			
Female	79.2	79.2	1.000
Male	20.8	20.8	
Age, mean (SD), years	45.1 (15.1)	45.1 (15.1)	1.000
<b>Race, %</b>			
Black or African American	7.7	11.5	
White	82.3	68.5	0.030
Other	10.0	20.0	
<b>U.S. region, %</b>			
Northeast	14.6	14.6	
Midwest	23.1	23.1	1.000
South	44.6	44.6	
West	17.7	17.7	
Charlson Comorbidity Index score, mean (SD)	0.4 (0.8)	0.3 (0.8)	0.457
BMI, mean (SD), lbs/in <sup>2</sup>	27.4 (7.1)	27.3 (6.4)	0.910
Education, more than high school, %	71.5	75.4	0.482

BMI, body mass index; IBS-C, irritable bowel syndrome with constipation; SD, standard deviation.

### Anxiety and Depression

The IBS-C Rome IV cohort reported significantly more moderate to severe anxiety than controls (41.5% vs. 29.2%;  $p=0.038$ ) and more moderate to severe depression than controls (49.2% vs. 31.5%;  $p=0.004$ ) [anxiety: GAD-7 score  $\geq 10$ ; depression: PHQ-9 score  $\geq 10$ ]

### Health-Related Quality of Life

The IBS-C Rome IV cohort reported significantly lower VR-12 Mental Component Summary (37.9 vs. 45.5;  $p<0.001$ ), Physical Component Summary (40.2 vs. 47.2;  $p<0.001$ ), and health utility (VR-6D) [0.6 vs. 0.7;  $p<0.001$ ] scores than controls (where lower scores indicate worse quality of life)

### All-Cause Healthcare Resource Utilization

A numerically greater proportion of patients in the IBS-C Rome IV cohort reported using healthcare resources in the past 6 months compared to controls (e.g., for primary care physicians, IBS-C Rome IV cohort: 52.3%; controls: 43.8%); however, it did not reach statistical significance

### Productivity

Absenteeism: A greater proportion of patients in the IBS-C Rome IV cohort vs. controls reported that they had missed or taken time off of work, school, or normal daily activities over the past 7 days due to mental or physical health (30.8% vs. 15.4%;  $p=0.003$ )

Presenteeism: A greater proportion of patients in the IBS-C Rome IV cohort vs. controls reported that they were impaired while working, attending school, or doing normal daily activities over the past 7 days due to mental or physical health (36.9% vs. 21.5%;  $p=0.006$ )

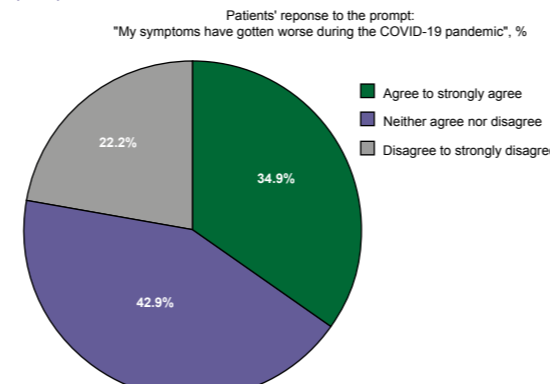
### Patient and Disease Characteristics

20.8% of the IBS-C Rome IV cohort reported being told by their healthcare provider (HCP) that they had IBS-C and not a constipation-related diagnosis; 47.7% reported being told they had IBS-C and/or a constipation-related diagnosis

Of those who could remember their age when symptoms first began ( $n=91$ ; 70.0%), the mean "time with" condition was 14.3 years

Over a third of the IBS-C Rome IV cohort indicated that their symptoms worsened during the COVID-19 pandemic (Figure 2)

Figure 2. IBS-C Rome IV cohort disease characteristics during the COVID-19 pandemic (n=126)



IBS-C, irritable bowel syndrome with constipation.

### Symptom Experience "in the Past 7 Days"

At 76.9%, "abdominal discomfort" was the most commonly reported symptom experienced by patients with IBS-C (Table 2)

At 67.4%, "straining while having a bowel movement" was the symptom most experienced "all of the time" or "most of the time" (Table 2)

At 6.6%, "incomplete feeling of bowel movement" had the highest mean severity (0="not at all severe", 10="extremely severe") among the five most frequently reported symptoms (Table 2)

Overall, "painful bowel movement" had the highest mean severity, at 6.7

Of all the symptoms patients experienced, abdominal pain was most frequently ranked as the most bothersome (30.0%) [Figure 3]

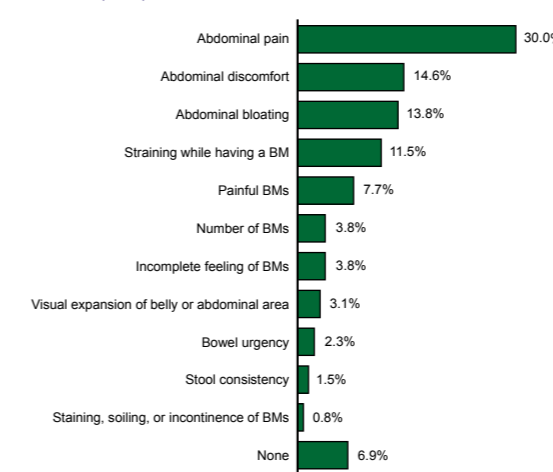
Table 2. Symptom frequency and severity for the five most frequently reported symptoms

Symptom	IBS-C Rome IV patients reporting symptom, %	Frequency "experienced all or most of the time", %	Severity, <sup>a</sup> mean
Abdominal discomfort (n=100)	76.9	37.0	5.6
Abdominal pain (n=97)	74.6	36.1	5.6
Straining while having a BM (n=95)	73.1	67.4	6.5
Abdominal bloating (n=84)	63.9	41.7	5.5
Incomplete feeling of BM (n=69)	53.1	60.9	6.6

<sup>a</sup>Frequency scale: All of the time, most of the time, sometimes, rarely, never; <sup>b</sup>Severity scale: 0="Not at all severe", 10="Extremely severe".

BM, bowel movement; IBS-C, irritable bowel syndrome with constipation.

Figure 3. Proportion of respondents ranking a given abdominal symptom as the most bothersome (n=100)<sup>a</sup>



<sup>a</sup>Sample sizes varied by response. BM, bowel movement.

### Medication Use

19.2% of patients with IBS-C reported currently taking a prescription medication, while 70.0% reported currently taking an over-the-counter (OTC) medication for their IBS-C symptoms (Table 3)

At 77.9%, "abdominal pain" was the most frequently reported symptom that led patients to take a medication

Patients currently taking a prescription medication with or without an OTC medication were more satisfied with the control of their symptoms, and with their HCP's management of their symptoms, than patients taking an OTC medication (Figure 4)

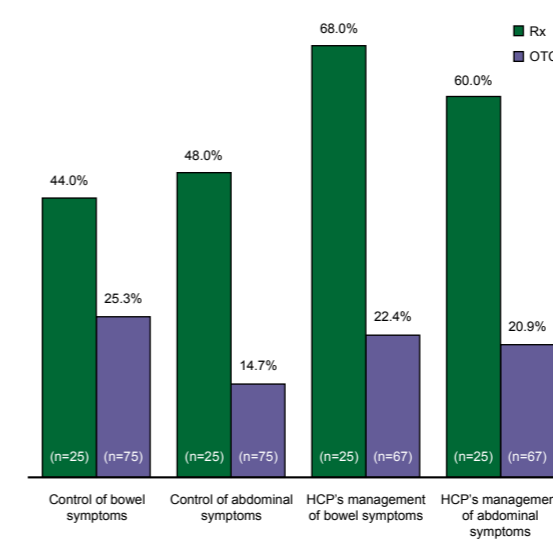
Of the 73 patients who had seen an HCP for their symptoms and had not taken a prescription medication, 72.6% never asked their HCP for prescription medication, primarily due to not wanting to take a prescription medication or OTC medications working well (both reported at 30.2%)

Table 3. Medications currently taken

	IBS-C Rome IV cohort (n=130)
Have you taken any medication to manage your BM-related symptoms and/or abdominal symptoms in the past 12 months?	
Prescription (n=25), %	19.2
Number of prescription medications currently taken, mean	1.2
OTC medication (n=91), %	70.0
Number of OTC medications currently taken, mean	2.1

BM, bowel movement; IBS-C, irritable bowel syndrome with constipation; OTC, over-the-counter.

Figure 4. Medication use and proportion of respondents satisfied with symptom control<sup>a</sup>



<sup>a</sup>Satisfaction: Satisfied, very satisfied, or extremely satisfied (other response options: extremely dissatisfied, very dissatisfied, dissatisfied, or neither satisfied nor dissatisfied); HCP, healthcare provider; OTC, over-the-counter; Rx, prescription.

### Care-Seeking Behaviors

22.3% of patients reported experiencing symptoms for "more than 4 years" before talking to their HCP about their symptoms; 36.9% reported experiencing symptoms for up to 1 year and 20.8% for 1 to 4 years

Of those who saw an HCP for their symptoms ( $n=116$ ), 53.4% of patients with IBS-C sought care in the past year. The most common reasons for seeking care were "Routine, scheduled visit" (56.5%) and "I didn't get adequate relief for and/or had worsening symptoms" (48.4%) [Table 4]

Nearly a quarter of patients with IBS-C reported canceling healthcare visits due to COVID-19 (Table 4)

Table 4. Care-seeking behaviors for bowel and/or abdominal symptoms

	IBS-C Rome IV cohort (n=130)
<b>What type of doctor have you seen for your symptoms?%, %</b>	
Primary care provider	87.9
Gastrointestinal specialist	49.1
Urologist	10.3
Gynecologist	8.6
Surgeon or colorectal surgeon, naturopath, dietician, or unsure	12.1
<b>Have you seen an HCP in the past 12 months for your symptoms?*</b>	
Yes, %	53.4
Number of visits, mean	2.8
<b>Have you canceled any visits due to COVID-19?*</b>	
Yes, %	23.3

\*Question answered by patients who reported seeing an HCP in the question "How long did you suffer with symptoms before seeing an HCP?" ( $n=116$ ). HCP, healthcare provider; IBS-C, irritable bowel syndrome with constipation.

## LIMITATIONS

- Data were self-reported and participants were limited to those with computer access
- Bowel and/or abdominal symptoms could have been attributed to more than just IBS-C
- Some outcomes had a small sample size and must be interpreted with caution
- This study did not include a pre-pandemic control group, which may have limited the ability to interpret these findings and fully understand the impact of the COVID-19 pandemic on outcomes and healthcare resource utilization

## CONCLUSIONS

- There remains a considerable disease burden and unmet need for patients with IBS-C; patients suffer from multiple bothersome symptoms and low rates of prescription medication use
- COVID-19 seems to have worsened IBS symptoms for many patients

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## DISCLOSURES

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